UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/248,438	02/11/99	MAYTOM M	PC10015AJTJ

HM12/0109

GREGG C BENSON
PFIZER INC
PATENT DEPARTMENT BOX 519
EASTERN POINT ROAD
GORTON CT 06340

EXAMINER	
WANG, S	
ART UNIT	**PAPER NUMBER**
1617	9

DATE MAILED: 01/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/248,438	Applicant(s) MAYTOM ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Receipt of the amendment and remarks submitted October 30, 2000 is acknowledged.

Double Patenting Rejection

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 2, 5-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-36 of copending Application No. 08/549,792. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons set forth in the prior office action.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1, 2, 5 and 9-10 rejected under 35 U.S.C. 102(a) as being anticipated by Derry et al. (Neurology, 1997, Vol 48, No. 3, page A215, IDS submitted Oct. 30, 2000).

Derry teach that sildenafil is useful for treatment of ED in men with spinal cord injury. See the abstract.

Claim Rejection 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 2, 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/28902 (of record) in view of Doherty et al. (of record) for reasons stated in the prior office action.

7. Claims 1, 2, and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derry et al. (Neurology, 1997, Vol. 48, No. 3, page A215, IDS submitted Oct. 30, 2000). Derry teach that sildenafil is useful for treatment of ED in men with spinal cord injury. See the abstract.

Derry does not teach expressly that the sildenafil is useful for men with spinal cord injury wherein the men exhibit essentially no residual erectile function.

However, it is well established that sildenafil selectively inhibits PDEv enzyme and lead to an elevation of cGMP levels in corpus cavernorsum tissue. The elevation of cGMP levels in corpus cavernorsum tissue cause the tissue relaxation and consequent penile erection. See, page 9, the last paragraph bridging to page 10 in WO 94/28902.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ sildenafil for the treatment of ED in men with spinal cord injury, who exhibits essentially no residual erectile function.

A person of ordinary skill in the art would have been motivated to employ sildenafil for the treatment of ED in men with spinal cord injury, who exhibits essentially no residual erectile function because the general established mechanism of sildenafil indicates it will be useful for treatment of ED in men with proper corpus cavernorsum tissue. A person of ordinary skill in the art would have reasonable expected that sildenafil would be useful for treatment of ED in men including those exhibits essentially no residual erectile function.

Applicants' remarks submitted October 30, 2000 have been fully considered, but are not persuasive as discussed below.

Regarding the remarks that there is no suggestion which would cause one of ordinary skill in the art to believe that a male with spinal cord injury would be able to achieve an erection (by administering sildenafil), note the claims is directed to the method of treating ED in man with SCI. i.e., the ED is not necessarily arise from SCI. It is well known that not all spinal cord injury will cause ED. Further, it is not seen how the vasoactive cGMP-PDE inhibiting compounds would function differently in man with spinal cord injury. Particularly, the process of vasoactive cGMP-PDE inhibiting is not seen to be directly associated with nervous system.

Regarding the remarks about the obvious rejection over WO 94/28902 in view of Doherty Jr. et al., note WO 94/28902 teaches the general mechanism of the treatment of ED by sildenafil which is not directly associated with nervous system, Doherty Jr. et al. suggested that cGMP-PDE inhibitor, sildenafil, is useful to treat erectile, sexual dysfunctions in various hosts,

including those suffering from neurogenic impotence associated with spinal cord injury. Further, the **oral** administration is not a limitation of the claims. Treatment of ED in male with essentially no residual erectile function and treatment of ED in male general differ in degree, not in kind. Therefore, they are not patentably distinct.

8. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on October 30, 2000 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shengjun Wang

AU 1617

January 3, 2001